



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 13 1998

Food and Drug Administration
Washington, DC 20204

Rec'd 3/26/98 j6

Mr. Steven R. Sumsion
General Counsel
NaturaLife Corporation
1375 North 1100 West
Springville, Utah 84663

Dear Mr. Sumsion:

This is in response to your letters of July 19, 1995, September 8, 1995 and April 1, 1996 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that NaturaLife Corporation is making the following claims, among others, for the products:

Cold Defense Formula

"Promotes well-being during the cold & flu season. NaturaLife's Cold Defense formula with *Echinacea purpurea* and Vitamin C helps promote well-being during the cold and flu season. Vitamin C provides antioxidant protection for many of the body's important enzyme systems. Additionally, Vitamin C plays an important role in the body's enzyme detoxification system."

Echinacea plus Golden Seal Root Blend

"*Echinacea purpurea* helps promote general well-being during the cold and flu season."

Echinacea plus Ester-C

"*Echinacea purpurea* helps promote general well-being during the cold and flu season."

Echinacea Root Combination

"*Echinacea purpurea* helps promote general well-being during the cold and flu season."

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Echinacea purpurea

"Echinacea purpurea helps promote general well-being during the cold and flu season."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products and, in the case of "Cold Defense Formula," the inclusion of the term "cold defense" in the product name, suggest that they are intended to prevent, treat or mitigate a disease, namely the common cold and influenza. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW340

Page 3 - Mr. Steven R. Sumsion

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:HFS-456;jel:3/13/98:docname:naturali.adv:disc26



April 1, 1996

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, NaturaLife Corporation wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Cold Defense Formula. The statement of nutritional support reads as follows:

"Promotes well-being during the cold & flu season. NaturaLife's Cold Defense formula with *Echinacea purpurea* and Vitamin C helps promote well-being during the cold and flu season. Vitamin C provides antioxidant protection for many of the body's important enzyme systems. Additionally, Vitamin C plays an important role in the body's enzyme detoxification system."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURALIFE CORPORATION

Gordon M. Walker
Regulatory Counsel

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NATURALIFE.

September 8, 1995

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, NaturaLife Corporation, wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea plus Golden Seal Root Blend. The statement of nutritional support reads as follows:

"Echinacea purpurea helps promote general well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURALIFE CORPORATION



Steven R. Sumsion

General Counsel
SEP 12 1995

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OFFICE OF SPECIAL
NUTRITIONALS, HFS-450

NATURALIFE.

September 8, 1995

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, NaturaLife Corporation, wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea plus Ester-C. The statement of nutritional support reads as follows:


"Echinacea purpurea helps promote general well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURALIFE CORPORATION



Steven R. Sumsion
General Counsel

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Steve/Letter/Kahl-NL

SEP 14 09:15 '95

NATURALIFE.

September 8, 1995

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, NaturaLife Corporation, wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea Root Combination. The statement of nutritional support reads as follows:

"Echinacea purpurea helps promote general well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURALIFE CORPORATION



Steven R. Sumsion
General Counsel

SEP 14 1995

RECEIVED BY MAIL
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450
Linda S. Kahl

NATURALIFE

July 19, 1995

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is *Echinacea purpurea*. The statement of nutritional support reads as follows:

"Echinacea purpurea helps promote general well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURALIFE CORPORATION



Steven R. Sumsion
General Counsel

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